REMARKS

Claims 1-15 were pending in this application at the time of the Office Action.

By this Amendment, Applicant has amended Claims 1, 5-11, and 13-15, and has added new Claims 16-36. Applicant respectfully submits that no new matter has been added by this amendment and that all amendments to the claims, including the addition of new claims, are fully supported by the originally filed application.

Claim Rejections:

Claims 1-4 and 12-15 stand rejected under 35 U.S.C. 102(b) as being anticipated by United States Patent Application Publication No. 2003/0021775 ("Freeman"). Claims 5-11 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Freeman in view of German Patent Publication No. 3935818 ("Neher").

While Applicant disagrees with the rejection, to advance prosecution, Applicant has amended Claim 1 to recite additional patentable limitations not anticipated by Freeman. Accordingly, Applicant submits that none of Claims 1-4 and 12-15 are anticipated by Freeman because Freeman does not disclose, teach, or suggest every element of each of these claims arranged as in each claim. *See* MPEP § 2131.

Amended Claim 1 is directed to an apparatus for aspirating, irrigating and/or cleansing wounds, comprising:

> a fluid flow path, comprising a conformable wound dressing, having a backing layer which is capable of forming a relatively fluid-tight seal or closure over a wound, at least one inlet passageway in communication with a space under the backing layer and at least one offtake passageway in communication with the space under the backing layer;
>
> a fluid reservoir in flow communication with the inlet passageway;
>
> means for supplying thermal energy to the fluid in the wound;
>
> means for providing simultaneous aspiration and irrigation of the wound such that irrigant may be supplied to fill the flow path from the fluid reservoir via the inlet passageway while fluid including wound exudate is aspirated by the first fluid moving device through the offtake passageway; and
>
> a regulator in communication with at least one of the inlet passageway and the offtake passageway and configured to at least regulate a rate of fluid flowing through at least one of the inlet passageway and the offtake passageway;
>
> wherein:
>
> the means for providing simultaneous aspiration and irrigation of the wound comprises a first fluid moving device applied downstream of and away

from the wound dressing and is configured to apply negative pressure to the wound; and

the regulator is configured to hold negative pressure on the wound at a steady level while simultaneous aspiration and irrigation is provided to the wound.

For example and without limitation, Applicant submits that Freeman does not disclose, teach, or suggest at least each of the following limitations, either alone or in combination with the other limitations of Claim 1:

1) wherein the means for providing simultaneous aspiration and irrigation of the wound comprises a first fluid moving device applied downstream of and away from the wound dressing;

2) wherein the first fluid moving device is *configured to apply negative pressure to the wound*; or

3) a regulator in communication with at least one of the inlet passageway and the offtake passageway and configured to at least regulate a rate of fluid flowing through at least one of the inlet passageway and the offtake passageway, wherein *the regulator is configured to hold negative pressure on the wound at a steady level while simultaneous aspiration and irrigation is provided to the wound.*

First, Applicant submits that Freeman does not disclose, teach, or suggest a means for providing simultaneous aspiration and irrigation of the wound comprising a first fluid moving device applied to fluid downstream of and away from the wound dressing. As shown in Figure 1 (reproduced below for reference), the pump 18 is upstream of the applicator 24, as opposed to being downstream of the wound dressing, as in Claim 1.

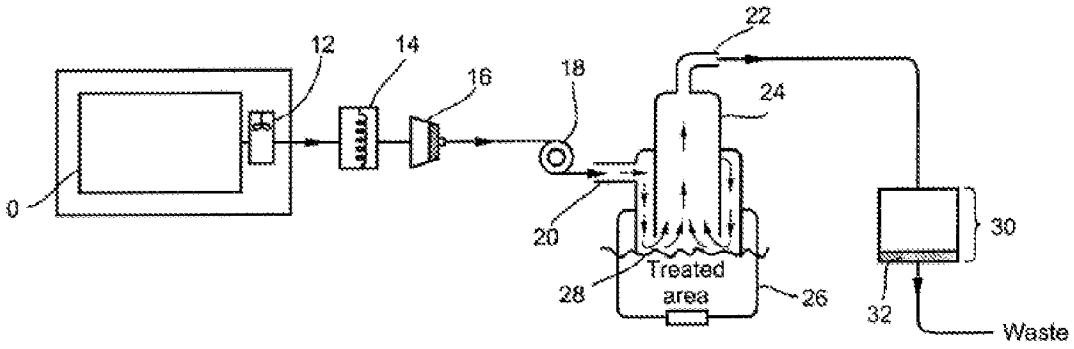

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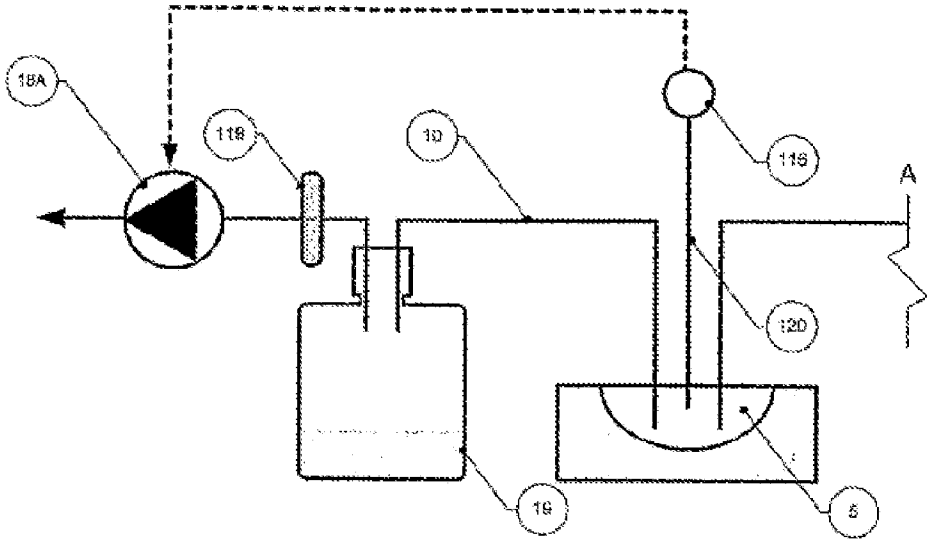
Fig. 1

Further, Applicant submits that Freeman does not disclose, teach, or suggest a first fluid moving device configured to apply *negative pressure* to the wound. To the contrary, Freeman discloses only a positive pressure tissue retrieval system that operates only under positive pressure. *See* Freeman, col. 5, ¶ [0073] ("In a further embodiment of the present invention, first reservoir 10 is in fluid communication with a pump 18 which serves for streaming the protease solution from first reservoir 10 to an applicator 24 (which is described in greater detail hereinafter) *under positive pressure*.") (italics added for emphasis).

Finally, Applicant submits that Freeman does not disclose, teach, or suggest a regulator in communication with at least one of the inlet passageway and the offtake passageway configured to at least regulate a rate of fluid flowing through at least one of the inlet passageway and the offtake passageway, wherein the regulator is *configured to hold negative pressure on the wound at a steady level while simultaneous aspiration and irrigation is provided to the wound.*

Holding the negative pressure level at a steady level has important therapeutic effects. Without limitation, examples of embodiments related to holding the negative pressure level at a steady level can be found at p. 70, lines 18-28.

> Referring to Figure 7C, this shows another alternative layout of the essentially identical, and identically numbered, components in Figure 7A downstream of point B in Figure 6A. The pressure monitor (116) is connected to a monitor offtake tube (120) and has a feedback connection to a variable-speed first device (18A), here a variable-speed pump, downstream of the filter (119), and the valve (16) in the fluid offtake tube (10) is omitted.
>
> This provides means for aspirate flow regulation and for holding the low negative pressure on the wound at a steady level. The operation of the apparatus is as described hereinbefore.



Additionally, p. 68, lines 22-26 of the Application as filed describe as follows:

A pressure monitor (116) connected to the fluid offtake tube (10) has a feedback connection to a bleed regulator, here a motorised rotary valve (117) on a bleed tube (118) running to and centrally penetrating the top of the aspirate collection vessel (19). This provides means for holding the low negative pressure on the wound at a steady level.

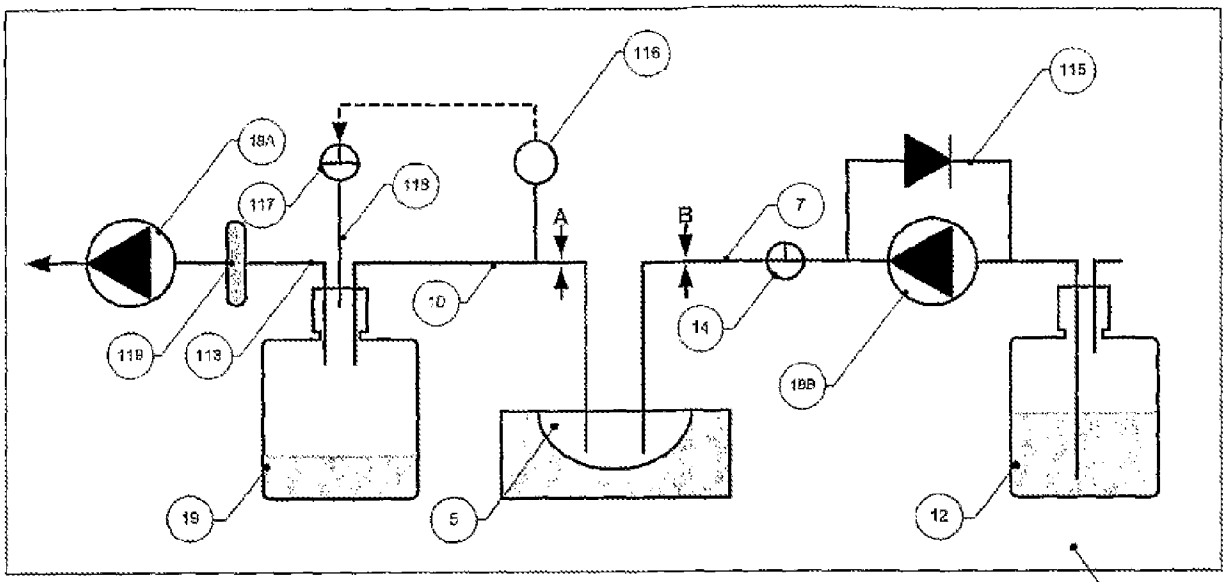


Figure 6

Additionally, without limitation, p. 69, lines 1-6 of the Application as filed describe in an alternative layout that a "bleed tube (118) runs to the air aspiration tube (113) downstream of the

filter (119), rather than into the aspirate collection vessel (19), … provid[ing] means for holding the low negative pressure on the wound at a steady level."

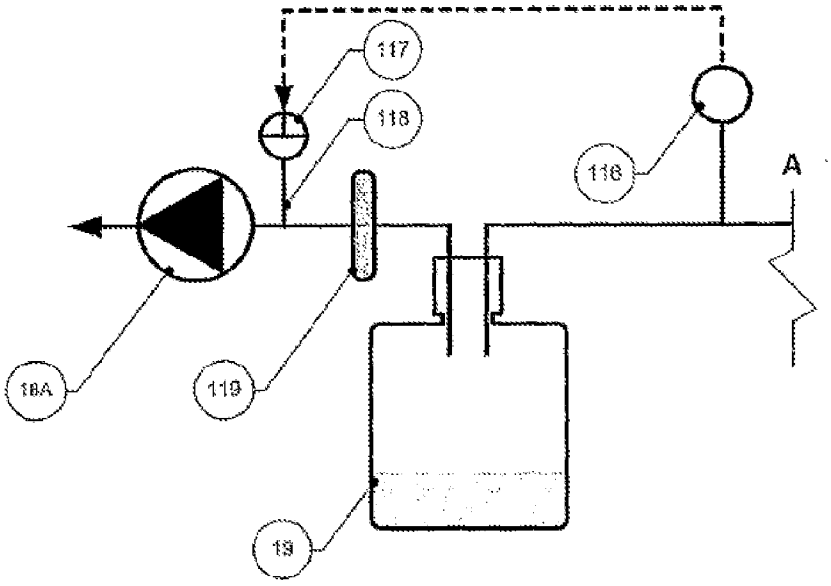


Figure 6b

Further, p. 69, line 33 – p. 70, line 3 of the Application as filed states as follows:

> The pressure monitor (116) is connected to a monitor offtake tube (120) and has a feedback connection to a means for aspirate flow regulation, here a motorised valve (16) in the air aspiration tube (113) downstream of the filter (119).
>
> This provides means for aspirate flow regulation and for holding the low negative pressure on the wound at a steady level. The operation of the apparatus is as described hereinbefore[.]

Because Freeman does not disclose, suggest, or teach applying negative pressure to a wound, Applicant submits that Freeman also does not disclose, suggest, or teach a regulator *configured to hold negative pressure on the wound at a steady level while simultaneous aspiration and irrigation is provided to the wound.*

Therefore, for at least these reasons, Applicant submits that Freeman does not anticipate Claim 1. Additionally, Applicant submits that the cited art does not anticipate or render obvious any of the claims depending from Claim 1, including the new claims presented herein, for at least

the reasons stated above for Claim 1, but also because each of the dependent claims sets forth additional patentable limitations not anticipated or rendered obvious by the cited art references.

Additionally, for reasons similar to those stated above for Claim 1, Applicant submits that the cited art references either alone or in combination do not anticipate or render obvious new Claim 21, or any claims depending therefrom. Claim 21 recites, *inter alia*, "a pressure monitor configured to monitor a level of negative pressure created by the apparatus under the backing layer" or a "regulator [] configured to maintain negative pressure on the wound *at a steady level* while simultaneous aspiration and irrigation is provided to the wound, *based on feedback provided by the pressure monitor* regarding the level of negative pressure between the backing layer and the wound."

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicant is not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicant reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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